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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/523,144

11/03/2005

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7590

11/24/2010

EXAMINER

DORNA, CARRIE R

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

11/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/523,144 | Applicant(s) NICITA, GIULIO | |
| | Examiner Carrie Dorna | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67 is/are allowed.
- 6) ☒ Claim(s) 68-78 and 80-82 is/are rejected.
- 7) ☒ Claim(s) 79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 1 August 2002. It is noted, however, that applicant has not filed a certified copy of the FI2002A000145 application as required by 35 U.S.C. 119(b).

Claim Objections

2. **Claims 71, 77, 79, 81, and 82** are objected to because of the following informalities:

- Claim 71 reads "said central hole U" in line 9, and should read --said central hole designated U--.
- Claims 79, 81, and 82 each read "a method for surgically implanting a device according to claim 74" in line 1, wherein claim 74 is directed to an apparatus. Since it appears that Applicant intends for claims 79, 81, and 82 to require a method, the Examiner recommends Applicant make each of claims 79, 81, and 82 independent claims incorporating all the limitations of claim 74 to avoid further objection or a potential rejection under 35 U.S.C. 112, fourth paragraph.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 68-78 and 80-82** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 recites the limitation "said central portion" in lines 15 and 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 74 recites the limitation "said central portion" in lines 13 and 16. There is insufficient antecedent basis for this limitation in the claim.

Claim 76 recites the limitation "said central portion" in lines 13 and 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 78 recites the limitation "said central portion" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 80 recites the limitation "the central part" in line 20. There is insufficient antecedent basis for this limitation in the claim.

Claim 81 recites the limitation "the central part " in line 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 81 recites the limitation "(f) conducting the other of said two steps in paragraph (c)" in line 18. There is insufficient antecedent basis for this limitation in the claim.

Claim 82 recites the limitation "the central part " in line 26. There is insufficient antecedent basis for this limitation in the claim.

Claims 69-72, 75, 77, and 79 are rejected as they are dependent on rejected claims 68, 74, or 76.

Response to Amendment

5. Applicant has apparently amended claim 67 such that the terms "front" and "rear", previously present in the claims filed 12 May 2010, have been replaced with "anterior" and "posterior", respectively. Although these amendments were not accompanied by the proper text markings, these amendments have been acknowledged.

Allowable Subject Matter

6. **Claim 67** is allowed.

7. **Claims 68-79 and 80-82** would be allowable if rewritten to overcome the objection(s) and rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

9. The following is an examiner's statement of reasons for allowance:

No prior art of record teach or fairly suggest an implantable device for treating female pelvic prolapse as claimed, comprising: a central body, a pair of anterior arms extending symmetrically outward from an anterior portion of said body transversely of a central longitudinal axis, a pair of posterior arms extending symmetrically downward and diverging from a posterior portion of said body, and a hole extending through said body located generally centrally in said body, said body including a cleft extending from the hole to a terminal edge of said body.

Furthermore, no prior art teach or fairly suggest a method of implanting the device as claimed, wherein the device is inserted into the vaginal cavity of the patient by means of vaginal surgery that comprises the steps of penetrating the tendineous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively to the right and to the left tendineous arch; passing respectively the rear arms by the sides of the uterus such that the central part surrounds the uterus; and bilaterally fixing the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. This application is in condition for allowance except for the following formal matters listed above:

- minor informalities in claims 77, 79, 81, and 82
- rejection of claims 68-78 and 80-82 under 35 U.S.C. 112, 2nd paragraph

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Art Unit: 3735

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Dorna whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D./
Examiner, Art Unit 3735